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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------------|--------------------------------------|----------------------|---------------------|------------------|
| 09/373,230 | 08/12/1999 | HARUKI OKMURA | OKAMURA=2E | 2359 |
| | 7590 11/07/200 D NEIMARK, P.L.L.C | EXAMINER | | |
| 624 NINTH ST | , | JIANG, DONG | | |
| SUITE 300 WASHINGTO | N, DC 20001-5303 | | ART UNIT | PAPER NUMBER |
| | | | 1646 | |
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| | | | MAIL DATE | DELIVERY MODE |
| | | | 11/07/2008 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief

| Application No. | | Applicant(s) | |
|-----------------|------------|---------------|--|
| 09/373,230 | | OKMURA ET AL. | |
| | Examiner | Art Unit | |
| | DONG JIANG | 1646 | |

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| The MAILING DATE of this communication appe | ars on the cover sheet with the c | correspondence add | ress |
| THE REPLY FILED 24 October 2008 FAILS TO PLACE THIS A | APPLICATION IN CONDITION FOR | R ALLOWANCE. | |
| 1. The reply was filed after a final rejection, but prior to or on application, applicant must timely file one of the following application in condition for allowance; (2) a Notice of Apper for Continued Examination (RCE) in compliance with 37 C periods: | the same day as filing a Notice of A replies: (1) an amendment, affidavited (with appeal fee) in compliance | Appeal. To avoid abar t, or other evidence, w with 37 CFR 41.31; or | hich places the (3) a Request |
| a) The period for reply expires 3_months from the mailing date b) The period for reply expires on: (1) the mailing date of this A no event, however, will the statutory period for reply expire la Examiner Note: If box 1 is checked, check either box (a) or (MONTHS OF THE FINAL REJECTION. See MPEP 706.07(| dvisory Action, or (2) the date set forth a ater than SIX MONTHS from the mailing b). ONLY CHECK BOX (b) WHEN THE | date of the final rejection | n. |
| Extensions of time may be obtained under 37 CFR 1.136(a). The date nave been filed is the date for purposes of determining the period of extender 37 CFR 1.17(a) is calculated from: (1) the expiration date of the set forth in (b) above, if checked. Any reply received by the Office later may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | on which the petition under 37 CFR 1.1. ension and the corresponding amount on thortened statutory period for reply origing than three months after the mailing date | of the fee. The appropria nally set in the final Office | ate extension fee e action; or (2) as |
| The Notice of Appeal was filed on A brief in comp filing the Notice of Appeal (37 CFR 41.37(a)), or any exter Notice of Appeal has been filed, any reply must be filed was AMENDMENTS. | nsion thereof (37 CFR 41.37(e)), to | avoid dismissal of the | |
| AMENDMENTS | | | |
| 3. The proposed amendment(s) filed after a final rejection, to the proposed amendment(s) filed after a final rejection, to the proposed amendment(s) filed after a final rejection, to the proposed filed filed amendment for the proposed filed f | nsideration and/or search (see NOTw); | E below); | |
| (d) ☐ They present additional claims without canceling a d | corresponding number of finally reje | cted claims. | |
| NOTE: See Continuation Sheet. (See 37 CFR 1.1 | 16 and 41.33(a)). | | |
| 4. ☐ The amendments are not in compliance with 37 CFR 1.12 5. ☐ Applicant's reply has overcome the following rejection(s): 6. ☐ Newly proposed or amended claim(s) would be all | · | | , |
| non-allowable claim(s). 7. For purposes of appeal, the proposed amendment(s): a) how the new or amended claims would be rejected is provided the status of the claim(s) is (or will be) as follows: Claim(s) allowed: Claim(s) objected to: Claim(s) rejected: 18.19 and 24-27. Claim(s) withdrawn from consideration: ACCIONATION OF ACCIONATION CONTINUES AND ACCIONATION CONTINUES AN | _ | be entered and an e | xplanation of |
| AFFIDAVIT OR OTHER EVIDENCE | t b - 5 tb d-t 5 5 12 NI- | tion of Annual colling | la a sustana d |
| The affidavit or other evidence filed after a final action, bu because applicant failed to provide a showing of good and was not earlier presented. See 37 CFR 1.116(e). | | | |
| The affidavit or other evidence filed after the date of filing entered because the affidavit or other evidence failed to o showing a good and sufficient reasons why it is necessary | vercome <u>all</u> rejections under appea and was not earlier presented. Se | ll and/or appellant fail ee 37 CFR 41.33(d)(1 | s to provide a). |
| 10. | n of the status of the claims after er | ntry is below or attach | ed. |
| The request for reconsideration has been considered bu See Continuation Sheet. | t does NOT place the application in | condition for allowan | ce because: |
| 12. ☐ Note the attached Information <i>Disclosure Statement</i> (s). (13. ☐ Other: | PTO/SB/08) Paper No(s). | | |
| | /Dong Jiang/ Primary Examiner, Art U | nit 1646 | |

Continuation of 3. NOTE: the newly amended claim 24 recites "which can be obtained by ... based on the amino acid sequence of SEQ ID NO:2", however, it does not specify how, structurally, the claimed protein differs from the amino acid sequence of SEQ ID NO:2. It is unclear how to make the changes based on SEQ ID NO:2, for example, where to change and what would be % identify of the claimed variants comparing to SEQ ID NO:2. As such, the amendment raises new issues that would require further consideration, and possible new grounds of rejections under 35 U.S.C. 112. Therefore, the proposed amendment(s) are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.

Continuation of 11. does NOT place the application in condition for allowance because:

With respect to the new matter rejection, claims 18 19, 26 and 27 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the previous Office Actions mailed on 2/21/08 and 8/14/08.

Applicants argue, in the response filed on 10/24/08, regarding the limitaiton "one or two" (claim 26), that while the disclosure of "one or more" does not provide an upper limit, it is clear that "more than one" must necessarily at least be "two" as intended by applicants and as would certainly be recognized and understood by those of ordinary skill in the art (page 6). Applicants argument has been fully considered, but is not persuasive because while "more" (in "one or more") may indicate "at least two", "two" (in "one or two") is not the same as "at least two". They differ in scope, and the specification does not provide sufficient basis for the limitation "one or two".

With respect to lack of written description rejection, claims 18, 19, 24 and 25 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention., for the reasons of record set forth in the previous Office Actions mailed on 8/8/07, 2/21/08 and 8/14/08.

Applicants argue, on page 8 of the response filed on 10/24/08, that at least with regard to "one or two" amino acid modifications recited in claim 26, SEQ ID NO:2 has 157 amino acid residues, thus, a variant of SEQ ID NO:2 that only has a one or two amino acid residue modification is at least 98.7% identical in sequence to SEQ ID NO:2, which situation is analogous to Example 14 in the USPTO's "Synopsis of Application of Written Description Guidelines". Applicants argument has been fully considered, but is not persuasive because it is irrelivent as the issue of "one or two" or claim 26 is not a part of this rejection.